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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,099	07/11/2001	Geetha Shankar	10602-013-999	1334

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1649

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,099

Applicant(s)

SHANKAR ET AL.

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Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-40 is/are allowed.
- 6) ☒ Claim(s) 28-37 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1) Claims 28 to 44 are pending in the instant application. Claim 37 has been amended as requested by Applicant in the correspondence filed 06 June of 2005.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 29 and 31 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 29 can be infringed by a nucleic acid that does not infringe the protein of claim 28. See M.P.E.P. 608.01(n)III. Applicant has traversed this objection on the premise that "[t]he test for a proper dependent claim under the fourth paragraph of 35 U.S.C. 9112 is whether the dependent claim includes every limitation of the claim from which it depends". Since the composition of claim 29 does not contain the chimeric protein of claim 28, it can not possibly include every limitation of claim 28. Correction is required.

5) The rejection of claims 38 to 42 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement and under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for those reasons of record in

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section 6 of the previous office action, is withdrawn in view of Applicant's assertion that the limitation "a transmembrane domain of a first Edg receptor" requires the presence of all seven "transmembrane strands" from that first Edg receptor within the structure of the claimed protein. This assertion is based upon the definition of the limitation "transmembrane domain" provided on page 10 of the instant specification. It is noted that the conventional use of the term "transmembrane domain", as employed in the art of receptor biology, is to identify a single membrane-spanning portion of a receptor protein. This conventional use is illustrated by the abstract of the Kim et al. publication (J. BIOL. CHEM. 269(46):28724-28731, 28 Nov. 1994), which states that "G-protein-coupled receptors mediate a wide variety of responses to extracellular stimuli in eucaryotic cells" and [b]inding of the ligand to these receptors is thought to involve contacts within a pocket formed by the seven transmembrane domains inferred from the sequences of these genes". However, because Applicant's unconventional but specific definition of the term "transmembrane domain" as encompassing all seven of the membrane spanning regions of a G protein-coupled receptor is not repugnant to the art, the rejection is withdrawn.

6) In view of the requirement by the definition of the limitation "transmembrane domain" that is provided by the instant specification, which requires the presence of all seven "transmembrane strands" from that first Edg receptor within the structure of the chimeric Edg receptor of claim 38, claims 38 to 40 are allowable as written.

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7) Claims 28 to 37 and 41 to 44 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 7 of the previous office action. As stated therein, claim 28 is vague and indefinite because the recited elements "Edg 1/3(ct)" and "Edg 8/4(ct)" do not appear to meet the limitation of comprising "a non-contiguous replacement of at least one intracellular domain strand of a first Edg receptor". The text on page 32 of the instant specification indicates that Edg 1/3(ct), for example, is a simple chimera comprising residues 1 to 314 of Edg-1 joined to residues 302 to 378 of Edg-3. There appears to be no "non-contiguous replacement" in Edg 1/3(ct) or Edg 8/4(ct). Claims 29 to 37 and 41 to 44 are vague and indefinite in so far as they depend from claim 28 for this element.

Applicant has traversed this rejection by explaining that Edg 1/3(i3ct) contains non-contiguous domain substitutions. This is not persuasive because the structure of **Edg 1/3(i3ct)** (Example 6.2) which is different from **Edg 1/3(ct)** (Example 6.1) and **Edg 8/4(ct)** (Example 6.6), is irrelevant to the instant rejection. This rejection is maintained because Edg 1/3(ct) and Edg 8/4(ct) do meet the limitation of comprising "a non-contiguous replacement of at least one intracellular domain strand of a first Edg receptor".

8) Claims 28 to 37 and 41 to 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Ancellin et al. publication (J. BIOL. CHEM. 274(27):18997-19002, 02 Jul. 1999) in view of any two or more of the Conway et al. (J. BIOL. CHEM. 275(27):20602-20609, 07 Jul. 1999), Schöth et al. (MOL. PHARM. 54:154-161, 1998),

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Wu et al. (J. BIOL. CHEM. 272(14):9037-9042, 04 Apr. 1997), Meng et al. (EUR. J. PHARM. 311:285-292, 1996), Holtmann et al. (J. BIOL. CHEM. 270(24):14394-14398, 16 Jun. 1995), Takagi et al. (J. BIOL. CHEM. 270(17):10072-10078, 28 Apr. 1995), Buggy et al. (J. BIOL. CHEM. 270(13):7474-7478, 1995), Kim et al. (J. BIOL. CHEM. 269(46):28724-28731, 28 Nov. 1994), Gether et al. (J. BIOL. CHEM. 268(11):7893-7898, 15 Apr. 1993) and Kobilka et al. (SCIENCE 240:1310-1316, 03 Jun. 1988, cited by Applicant) publications for those reasons of record as applied to claims 1 to 27 in the and in the office action mailed 26 September of 2003 and as applied to claims 28 to 44 in section 9 of the previous office action. As stated therein, the instant claims are drawn to a chimeric Edg receptor comprising domains from Edg1 and Edg3, and an assay employing it. Whereas the elected species of chimeric receptor, Edg 1/3(i3ct), is free of the art, these claims specifically encompass the embodiments recited therein as Edg 1/3(ct) and Edg 8/4(ct), which are obvious in view of the cited combination of references for those reasons of record.

Applicant has traversed this rejection on the basis that "[s]ince the Ancellin reference discloses intact Edg receptors, not chimeras, and the Conway, Schioth, Je, Meng, Holtman, Takagi, Buggy, Kim, Geethar, and Kobilka references only disclose chimeric constructs that are not explicitly recited by the claims, one of skill in the art would not expect to achieve success in producing the claimed invention by combining the cited references, and therefore would not be motivated to do so". This argument is not persuasive because the instant rejection is not based upon anticipation, it is based upon obviousness. To argue that one has no reasonable expectation that something

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can be done simply because it hasn't been done is illogical and, in the instant case, completely ignores the preponderance of evidence of record, which shows that the construction of a series of chimeric G protein-coupled receptors composed of various combinations of structural domains from two different but related G protein-coupled receptors having distinct pharmacological properties for the purpose of identifying those structural domains in each of those two related receptors that are responsible for the specific pharmacological properties of that receptor was a procedure that was routinely practiced in the art at the time that the instant invention was made.

Applicant's assertion that "[t]he recitation of a transmembrane domain and an extracellular domain from a first Edg receptor, implies non-contiguous replacement of the intracellular strands to form the chimeric intracellular domain" is incorrect. A claim limitation is given its broadest reasonable interpretation, and any reasonable interpretation of the limitation "a transmembrane domain and an extracellular domain from a first Edg receptor" does not require that those domains be non-contiguous. Applicant is arguing a limitation that is neither explicitly nor implicitly recited in these claims. Further, the continued presence of the express embodiments Edg 1/3(ct) and Edg 8/4(ct), which contain no non-contiguous domain replacements, in the claims shows that this limitation is not implied.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

9) Applicant's arguments filed 06 June of 2005 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

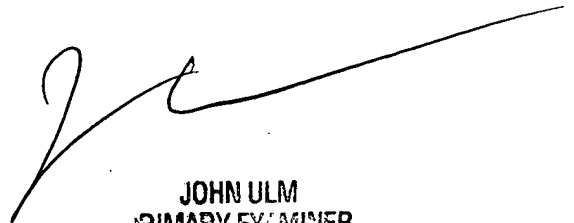
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1649